Sysmex® XN-3100™ Automated Hematology System

Principle

The Sysmex XN-3100 is an integrated system that incorporates hematology analytical modules as well as automated slidemaker/stainer.

The analytical module is a quantitative automated hematology analyzer for *in vitro* diagnostic use in determining 31 whole blood diagnostic parameters and 7 body fluid diagnostic parameters. Examination of the numerical and/or morphological findings of the complete blood count by the physician are useful in the diagnosis of disease states such as anemias, leukemias, allergic reactions, viral, bacterial, and parasitic infections. The analyzer performs hematology analysis according to the hydrodynamic focusing (DC Detection), flow cytometry method (semiconductor laser), and SLS-hemoglobin method.

The device counts and sizes red blood cells (RBC) and platelets (PLT) using electronic resistance detection. Hematocrit (HCT) is measured as a ratio of the total RBC volume to whole blood using cumulative pulse height detection. Hemoglobin (HGB) is converted to SLS-hemoglobin and read photometrically.

The white blood cell (WBC) count, differential (DIFF), reticulocytes (RET), nucleated red blood cells (NRBC) and fluorescent platelets (PLT-F) are all evaluated using flow cytometry with a semiconductor laser exploiting the differences in cell size, complexity and RNA / DNA content. Forward scattered light provides information on blood cell size and Lateral scattered light provides information on the cell interior such as the size of the nucleus. Lateral fluorescent light intensity increases as the concentration of the stain becomes higher. By measuring the intensity of the fluorescence emitted, information is obtained on the degree of blood cell staining. Fluorescent light is emitted in all directions. The XN detects the fluorescent light that is emitted sideways.

The Sysmex SP-50 is a fully automated hematology slide preparation and staining system. Whole blood specimens are mixed and aspirated, and a wedge type blood smear is prepared using hematocrit information from the Sysmex XN to determine optimum smearing criteria. The dried smear is automatically loaded into an individual slide cassette and is then advanced to the staining area. In the staining area, stain and buffer are dispensed into the cassette at operator-defined intervals. The system also provides a manual mode operation where pre-made smears may be added to be stained. The unit is self-monitoring and alarms when operation is interrupted. Slides prepared by the Sysmex SP-50 are used for differentiation and morphologic evaluation of cellular elements of whole blood.

The Sysmex DI-60 is an automated digital cell locating device intended to aid morphologists in the location and classification of white blood cells and non-WBC's such as NRBC, the characterization of red cell morphology and estimation of platelets in peripheral blood. The DI-60 scans one slide at a time and the cells are analyzed by the Artificial Neural Network (ANN) and assigned a pre-classification. The operator reviews images to confirm or modify suggested classification of cell types.

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Scope

This procedure is intended for CLS staff to perform CBC tests on properly collected plasma/serum samples from patients.

Specimen Requirements

A. Required specimen: Whole blood should be collected in EDTA-2K or EDTA-3K anticoagulant.

B. Specimen volumes required:

1. Optimal draw is a 12 x 75 mm tube filled to capacity
2. A minimum of 1 mL of whole blood is required for sampler analysis.
3. Manual analysis whole blood mode
   a. Closed tube – 1 mL
   b. Open tube – 300 µL
   c. Open microtube – 160 µL
4. Manual analysis – SP-50
   a. Closed tube smear and staining – 500 µL minimum sample volume, 70 µL is aspirated.
   b. Open tube smear and staining - 300 µL minimum sample volume, 70 µL is aspirated

C. Unacceptable specimens including those listed below must be redrawn:

1. Clotted samples or those containing clots, fibrin strands, or platelet clumps. All specimens should be checked visually for obvious clots prior to sampling by the analyzer.
2. Grossly hemolyzed samples
3. Samples drawn above an IV line

D. Characteristics that may affect test results: lipemia, icterus, and cold agglutinins.

E. Stored Specimen Stability:

1. Stored at 4-8°C, EDTA blood samples with normal results may be analyzed up to 48 hours without significant loss of differential stability.
2. Sample stability at room temperature is 24 hours. Samples stored at room temperature may exhibit an increase in MCV after 24 hours, which may be minimized by refrigeration.
3. Allow refrigerated samples to come to room temperature and mix well before analysis.

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Reagents

A. Supplies

1. Deionized water
2. Test tubes
3. Plastic squeeze bottles
4. CELLCLEAN® AUTO
5. Sysmex reagents
6. Commercial controls; XN CHECK™
7. Alcohol prep pads, isopropyl. Used to clean SP-50 spreader glass
8. Microscope slides, frosted with rounded / clipped corners

B. Sysmex Reagents

1. Sysmex reagents and CELLCLEAN AUTO are used on the Sysmex XN-Series modules.
2. All reagents are used at room temperature and are to be used within the manufacturer's expiration date on each container.
3. Record date received and date opened on container.
   All reagents are azide free and are intended for *in vitro* diagnostic use only. **Do not ingest.**

XN REAGENTS	OPEN EXPIRATION
CELLPACK DCL	60 Days
CELLPACK DST	60 Days
CELLPACK DFL	60 Days
SULFOLYSER	90 Days (5.0L)
Lysercell WNR	60 Days
Fluorocell WNR	90 Days
Lysercell WDF	90 Days
Fluorocell WDF	90 Days
Fluorocell RET	90 Days
Fluorocell PLT	90 Days

SP-50 REAGENTS	
Stain – Sysmex Color Wright Stain	
Concentrated Phosphate Buffer – pH 6.8	
Methyl Alcohol	
NERL Box water	
CELLPACK DCL	60 Days

C. Diluents

1. **CELLPACK DCL**: Whole blood diluent for use in hematology analyzers and for use as a rinsing agent for the spreader glass, sample pipette, and piercer on the SP-50.
2. **CELLPACK DST (DST):** Concentrated diluent of reagent for use in hematology analyzers.
3. **CELLPACK DFL (DFL):** Whole blood diluent for use in hematology analyzers; used in combination with Fluorocell™ RET for the analysis of reticulocytes, or with Fluorocell PLT for the analysis of platelets by flow cytometry method using a semiconductor laser.

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Reagents, continued

D. Lysing Reagents

1. **SULFOLYSER (SLS):** Reagent for the automated determination of hemoglobin concentration of blood. Sulfolyser is a lysing reagent that releases the hemoglobin to be measured by the SLS hemoglobin method.
2. **Lysercell WNR:** Reagent product to be combined and used with Fluorocell WNR. By hemolyzing red blood cells with Lysercell WNR and by differentiating white blood cells (non-basophil), basophils, and nucleated red blood cells with Lysercell WNR and Fluorocell WNR, the white blood cell count, basophil count, basophil percentage, nucleated red blood cell count, and nucleated red blood cell percentage are analyzed.
3. **Lysercell WDF:** Reagent product to be combined and used with Fluorocell WDF. By hemolyzing red blood cells with Lysercell WDF and dying the white blood cell component with Fluorocell WDF, the counts and percentages of neutrophils, immature granulocytes, lymphocytes, monocytes, and eosinophils are analyzed.

E. Staining Reagents

1. **Fluorocell WNR:** Used to stain the nucleated cells in diluted and lysed blood samples for determination of white blood cell count, nucleated red blood cell count and basophil count in blood.
2. **Fluorocell WDF:** Used to stain the leukocytes in diluted and lysed blood samples for determination of differential count in blood.
3. **Fluorocell RET:** Used to stain the reticulocytes in diluted blood samples for the assay of reticulocyte count, reticulocyte percent in blood.
4. **Fluorocell PLT:** Used to stain the platelets in diluted blood samples for the assay of platelet counts in blood.

F. Cleaning Agent

1. **CELLCLEAN AUTO:** Detergent for fully automated hematology analyzers. To be used as a strong alkaline detergent to remove lysing reagents, cellular residuals, and blood proteins remaining in the hydraulics of the analyzer. For use as a cleaning fluid for the hematology analyzers and the SP-50.

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Reagent Replacement

When the reagent runs out during analysis, the analysis is paused, and an error message appears in the analyzer area of the Control menu.

Follow steps below:

A. Display the **[Reagent Replacement]** dialog box to replace the reagent.

a. Select the help button on the control menu
b. Select **[Execute].** Remaining Reagent Volume indicator appears.

B. To replace a new diluent / hemolytic agent:

a. Display the **[Reagent Replacement]** dialog box.
b. Remove the cap from the new reagent container. Confirm the reagent has not expired.
c. Input the reagent code (barcode)
   - Place the cursor in the reagent code field
   - Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code.
   - Select **[OK]**
d. Remove the cap from the old reagent container.
e. Pull out the dispensing set straight up.
f. Insert the dispensing set straight into the new container.
g. Close the cap.
h. Select **[Execute]**. Reagent replacement starts. When complete, the dialog box closes automatically.

C. To replace CELLPACK DST with an RU-20:

a. Display the RU-20 Maintenance menu
b. Select **[Replace Reagent].**
c. Remove the cap from the new reagent container. Confirm that reagent has not expired.
d. Input the reagent code (barcode)
   - Place the cursor in the reagent code field
   - Scan the reagent code on the outer box of the new reagent with the hand-held barcode reader or manually enter the reagent code.
   - Select **[OK].**
e. Remove the cap from the old reagent container.
f. Pull out the dispensing set straight up.
g. Insert the dispensing set straight into the new container.
h. Close the cap.
i. Select **[Execute]**. Reagent replacement starts. When complete, the dialog box closes automatically.

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Reagent Replacement, continued

D. To replace dye:

1. Display the **[Reagent Replacement]** dialog box.
2. Prepare the new reagent cartridge. Confirm the reagent has not expired.
3. Open the top front cover.
4. Pull up the cover from the reagent that is to be replaced. A **Help** dialog box appears in the IPU screen.
5. Remove the old reagent cartridge from its holder.
6. Insert the new reagent cartridge into the holder.
   a. Make sure the color of the label on the new reagent cartridge matches the color of the dye cover and install. Analyzer will beep as confirmation of new reagent installation.
   b. If the wrong reagent is installed, the analyzer beeps repeatedly and the **Help** dialog box appears in the IPU screen.
7. Pull down the cover on the reagent until you hear a click. The **Help** dialog box closes automatically.
   a. The ID of the new reagent is read automatically, and the information is registered.
8. Close the top front cover. Reagent replacement starts. When complete, the reagent replacement window closes automatically.

E. SP-50 Reagent Replacement

The following is a list of replacement messages and the requiring replacement:

MESSAGE	REAGENT
Out of CELLPACK DCL	CELLPACK DCL
Out of Stain Solution 1	Stain 1
Out of rinse water	Deionized Water
Out of methanol	Methanol
Out of phosphate buffer	Buffer

1. When a reagent container is empty, an error occurs and an alarm sound.
2. Touch **[Execute]** in the **[HELP]** dialog box.
3. Load the new reagent using a clean technique. Avoid placing spout kits or sensors on a contaminated surface.
4. Input the new reagent information using either of the following procedures:

   a. Input the reagent code using a handheld barcode scanner
   b. Manually enter the reagent code
      - Touch the name of the reagent to be replaced in the **[Replace Reagent]** dialog box.
      - Select the **[Replace the Reagent]** checkbox.
      - Enter the **[Reagent code]** and touch **[OK]**.

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Calibration & Precision

Refer to Sysmex XN Calibration and Precision Procedure.

Quality Control

For detailed QC procedure refer to Sysmex XN QC Procedure.

Frequency of Control use and Review

1. XN CHECK control levels: **ALL 3 levels** will be performed daily. All levels of controls should be analyzed at least once in every eight-hour shift for **both** XNs.
2. SP-50 QC slide will be evaluated daily on the Cellavision.

Note: Since the XN only has one sample pathway, i.e. it only has one needle for aspiration, it does not matter whether it is done in **AUTO or MANUAL** mode.

Operating Procedure

A. Start-Up Procedure:

1. Checks prior to turning on:
   a. Place completed samples into final storage area for the lab.
   b. Gather and relocate all empty racks to designated processing or sample loading area.
   c. Verify waste container is empty. Replace if needed.
   d. Verify network/host connections are properly working.
   e. Ensure that the SP-50 towers (slide supply cassettes) have sufficient slides. Fill with glass slides.
   f. Ensure empty grey magazines are loaded onto the SP-50 feed out block.

2. Start up the DI-60:
   a. Switch on the DI-60 using the main switch located on the front of the unit.
   b. Switch on the system computer (IPU).
   c. Wait until the status lamp on the DI-60 stops flashing and is continually lit.
   d. In the Log-on dialog box type your NUID and Password.
   e. Select the appropriate database from the drop-down menu. Click **[OK].**
   f. Ensure several empty blue magazines are in the magazine storage unit on the CF-70.
   g. System control View displays. Make certain the start-up test passes. The DI-60 will not process slides if the start-up test fails.

3. Turning ON the entire system
   a. Verify that all power switches for each device are in the **ON** position
   b. Press the green master switch to power **ON** the entire system.

4. Log on to the XN-IPU
   a. To logon, enter: username: **XN** and password: **XN**

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Operating Procedure, continued

5. Analyzers, SP-50, and CF-70 self-checks

a. XN: Initialization of the mechanical parts; Rinse; Temperature stabilization; Background Check (up to 3 times)

XN Acceptable Background Counts	
Parameters	**Acceptable Limit**
WBC-N	0.10 x 10^3/ µL
WBC-D	0.10 x 10^3/ µL
RBC	0.02 x 10^6/µL
HGB	0.1 g/dL
PLT-I	10 x 10^3/ µL
PLT-F	3 x 10^3/ µL

b. SP-50/CF-70: System check to evaluate internal stored data files; shutdown check to determine whether shutdown was performed properly, a mechanical initialization sequence. LED light turns green when READY.

6. Perform QC for all XN analyzers.

B. Patient Sample Processing:

1. System Analysis (sampler analysis)

Step	Action
1	Make sure the analyzer and the sampler are in **READY** state.
2	Check that tube holder has retracted into the analyzer, press mode button if necessary.
3	Place barcoded sample(s) in rack(s) in the feeder.
4	Rack(s) will be automatically pushed forward and routed to analyzers.
5	Samples will run, results will be displayed in the IPU.
6	Sysmex WAM will determine repeat or reflex testing.
7	Rack will run in reverse to perform repeat or reflex testing on the same XN.
8	If smear is required: • Rack will be transported to SP-50 via feeder line and samples will be aspirated by SP-50. • SP-50 prepares, and stains smears and transports the prepared smears in grey magazines. • Grey magazines will then be shuttled via CF-70 to the DI-60. • Once orders are processed on the DI-60, the completed slides will exit the DI-60 in BLUE magazines to the front magazine storage unit. • If no smears are required, rack will be transported to the collector unit without stopping at the SP-50.
9	Remove the rack(s) when analysis in completed.

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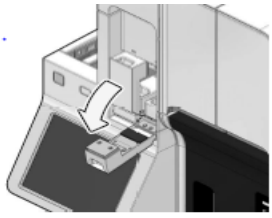
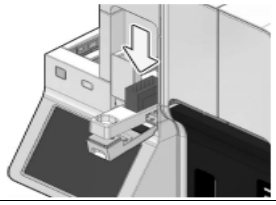
2. Manual Analysis

Step	Action
1	Check the Status indicator LED on the analyzer to confirm analyzer is in **READY** state.
2	Press the mode switch to eject the tube holder.
3	Select the Change Analysis Mode button on the control menu.
4	Select analysis mode: **[Whole blood]** is selected when whole blood is being analyzed **[Low WBC]** Select this to perform low WBC analysis on whole blood **[Pre-Dilution]** select when running 1:7 pre-diluted blood
5	Select **[OK]**
6	Properly mix the specimen and place in the tube holder. • If running microtainer, remove the cap using caution to avoid splattering.
7	Press the start switch on the analyzer. • The tube holder will slide in and the sample will be aspirated • When the analysis is complete, the tube holder slides out
8	Remove the sample, repeat steps for additional samples.
9	Review results in IPU to determine whether repeat or reflex testing is required. Rerun sample if required. Make smear if required.

3. SP-50 Manual Mode – [Smearing and Staining] / [Smearing Only]

In **[Smearing & staining]** mode, slide glass printing, smear preparation, and staining are performed. In **[Smearing]** mode, only slide glass printing and smearing are performed.

For **[Smearing & staining]** mode, proceed to Step #3.

Step	Action	
1	Open the manual magazine holder cover if the instrument is in [Smearing] mode. Open the cover forward. You can use either the left or right manual magazine holder. Pull out the magazine holder.	
2	Load an empty gray magazine in the manual magazine holder. Push in the manual magazine holder. Close the cover.	

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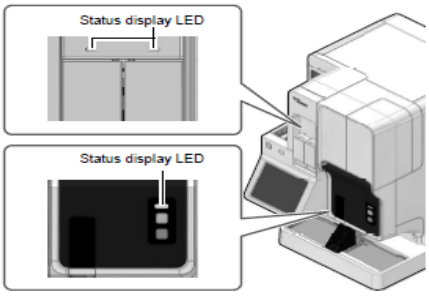
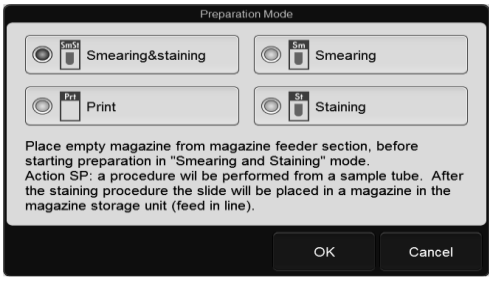
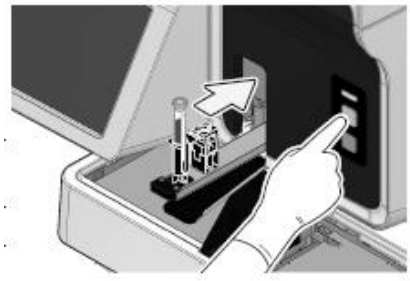
3	Check the instrument and status display LED of manual magazine holder. If the status display LED is not lit green, wait until it lights. 
4	If the sample holder has not been ejected out, press the mode switch on the main unit front side. The sample holder slides out forward.
5	Touch **[Mode]** in the status area. The dialog box on the right appears. 
6	Touch **[Smearing & staining]** or **[Smearing]** depending on what you need.
7	Touch **[OK].** Dialog box closes, the slide preparation mode is enabled.
8	Mix the sample and put the sample tube in the sampler holder.
9	Press the start switch (BLUE) on the main unit. The sample holder is retracted, and smear preparation starts. When the sample aspiration is completed, the sample holder is ejected out forward automatically. 
10	Remove the sample tube from the sample holder.
11	Press the mode switch on the main unit front side. The sample holder retracted into the instrument.
12	Remove the prepared smears. • When preparation of all smears is completed, the magazine containing the sample(s) is ejected to the storage location for the slide preparation mode used. Retrieve the magazine that contains the smears.

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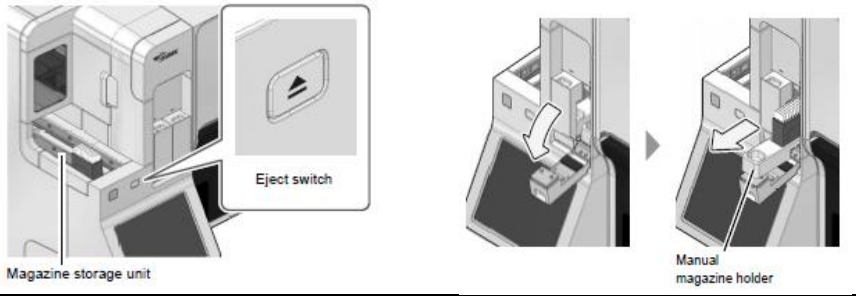
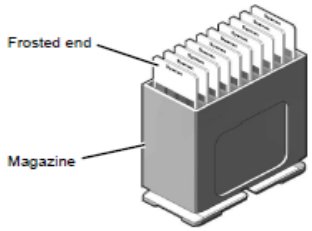
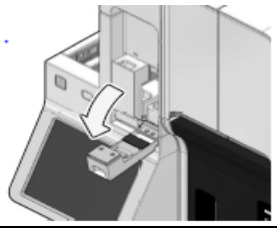
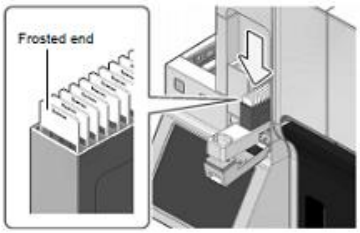
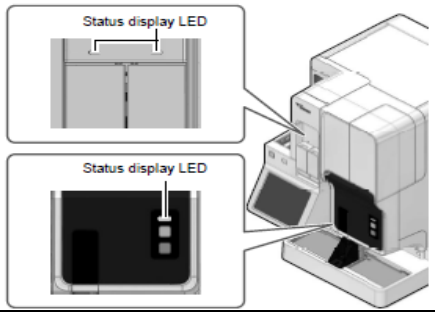
	[Smearing & staining] **[Smearing]** 

5. SP-50 Manual Mode – Stain Only

Step	Action	
1	Load smeared slide glasses to the magazine so that they face the same direction. With the frosted end of the slide facing to the front, the slide is successively stained from the front.	
2	Open the manual magazine holder cover if the instrument is in [Smearing] mode. Open the cover forward. You can use either the left or right manual magazine holder. Pull out the magazine holder.	
3	Load the magazine that holds the slide glass in the manual magazine holder. Make sure that the frosted end faces forward. Push in the manual magazine holder and close the cover.	
4	Check the instrument and status display LED of manual magazine holder. If the status display LED is not lit green, wait until it lights.	

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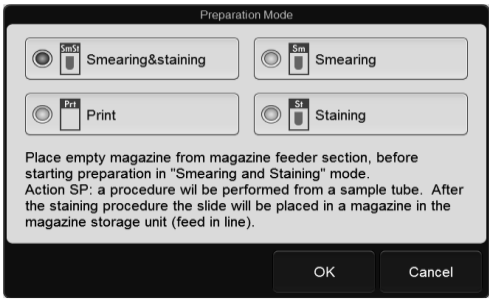
5	Touch **[Mode]** in the status area. The dialog box on the right appears. 
6	Touch **[Staining]** and touch **[OK]**. Dialog box closes, the slide preparation mode is enabled.

NOTE: For ALL manually prepared slides that need to go to DI-60, you will have to manually put the grey magazine(s) with slides to the DI-60 for processing and reading.

C. Shutdown

CELLCLEAN AUTO is used to shut down the entire system. Refer to the XN-3100 *Instructions for Use* for detailed, illustrated procedures.

Step	Action
1	Confirm analyzers, conveyors, and SP-50 are at ready.
2	Confirm tube holders are retracted into the analyzers.
3	Obtain empty blue maintenance rack labeled SRRA00. Place one tube of CELLCLEAN AUTO in the rack for each module or SP-50 requiring maintenance beginning with position 10 and load backwards.
4	Place rack on feeder unit, sampler unit will auto-start.
5	XN on-board maintenance history will auto-populate.
6	Document shutdown on the SP maintenance log.

D. Maintenance

Document all maintenance procedures on the appropriate log sheet for the SP-50. Maintenance performed on the XN will be automatically tracked in the maintenance history.

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- **DAILY PREVENTIVE MAINTENANCE**

1. Shutdown

1.1) Shutdown entire system – Sampler Mode

a. Confirm that all XNs, conveyor unit and SP-50 are at ready and not in "off-line" mode.
b. Confirm glass slides are loaded and an empty magazine is loaded in the manual magazine holder.
c. Confirm tube holders are retracted into the XNs.
d. Use 2 blue maintenance racks labeled SRRA01/SRRA02.
   - Place one tube of CELLCLEAN AUTO in the rack for each module requiring maintenance beginning with position 10 and load backwards, e.g., if there are 4 XN modules – load 4 tubes of CELLCLEAN AUTO in positions 7-10.
e. Load the racks onto the feeder, rack will automatically convey to the analyzers.
f. Shutdown of all XNs is performed automatically.
g. Remove the blue maintenance racks.
h. SP-50 will be shutdown manually using [Shutdown1], refer to Section 1.4, manual procedure below.

1.2) Daily Cleaning – Manual Mode - XN Analyzers only

Daily "Cleaning" can be used as an alternative to the daily "Shutdown" procedure to keep one analyzer up and running at all times and to allow for rack flow to the alternate analyzer.

a. Make sure the analyzer is in the "Ready" state
b. Click the analyzer menu button
c. Select **[Maintenance]**
d. Select **[Cleaning]**
e. The tube holder will slide out. Place a vial of CELLCLEAN AUTO in the sample tube holder.
f. Press the blue start switch. This will take about 20 minutes.
g. Remove the tube of CELLCLEAN AUTO from the rack and discard.

1.3) Power Off IPU

a. Make sure all racks have finished and the system is at 'Ready'
b. Touch [Exit IPU] on the menu screen of the XN software
c. Touch [Yes] to confirm
   - This will exit the XN software
d. From the Windows desktop, select [Shutdown] from the start Menu
   - This will turn off the XN-IPU and the connected XN analyzers

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1.4) Shutting down the conveyors

If the separate shutdown procedures for the XN's have already been completed, you can turn OFF the conveyor units.

a. Hold down the green master start-up switch on the conveyor for approximately 3 seconds until the status LED light turns off.
b. The conveyors will now be turned off.

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1.5) Shutdown – SP-50 – Manual Mode

a. Confirm glass slides are loaded and there is sufficient reagent.
b. Confirm an empty magazine is loaded in the manual magazine holder.
c. Touch **[Menu]** on the tool bar
d. Touch **[Shutdown]**. A dialog box appears, and the sample tube holder slides forward.
   - You may select **[Shutdown1]** or **[Shutdown2]**.
e. Set CELLCLEAN AUTO in the sample tube holder
f. Press the start switch on the main unit. The sample tube holder is retracted into the instrument.
g. Shutdown is automatically performed. Once the CELLCLEAN AUTO is aspirated, the sample tube holder will be ejected. Remove the used CELLCLEAN AUTO and discard.
h. Once the shutdown has completed, the analyzer will turn off.
i. Remove the glass slide used for cleaning in the manual magazine.

2. **Check/Empty stain waste container for SP-50.** The hematology CLS will check the waste container at the start of each shift. Replace/empty waste container as needed.

3. **Inspect the Staining Pool – SP-50**
   The staining pools may collect a buildup of stain precipitate daily. After the analyzer completes the shutdown procedure, inspect the staining pool for stain precipitate and wipe clean with methanol if necessary.
4. **Check reagents and refill slides**

- **WEEKLY PREVENTIVE MAINTENANCE**

1. **Perform Shutdown 2** weekly on SP-50 manually. Follow the procedure on Section 1.4, choose the **[Shutdown2]** option.

2. **Clean the Staining Pool**
   When **[Shutdown2]** is complete, then the staining pool can be cleaned.

a. Prepare a container with methanol to use for the cleaning process
b. Open the staining pool cover forward and down, lift and remove the 2 staining pools.
c. Use a lint free lab wipe or gauze to lift the stain pool from the stain area to avoid splashes or drips of residual stain.
d. Put the staining pools in the container for cleaning and lightly stir to clean.
e. Add methanol to the container covering both staining pools completely for no more than 5 minutes.
f. Dry the staining pools with a lint free cloth or gauze.
g. Install the 2 staining pools. Replace staining pool covers and close the staining part cover.

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3. Clean the spreader glass

To maintain smear quality for a longer period, the instrument cleans the spreader glass with CELLCLEAN AUTO each time shutdown is performed. However, spreader glass debris should be manually wiped off once a week.

a. Touch **[Maintenance]** in the menu screen.
b. Touch **[Replacement]**.
c. Touch **[replace spread glass]**.
d. Make sure that the smear unit cover is closed and touch **[OK]**.
e. Open the slide set unit cover.
f. Remove the slide supply cassette from the slide set unit.
g. Close the slide set unit cover.
h. Open the smear unit cover.
i. Rotate the fan forward and down. The spreader glass is directly behind the fan.
j. Wipe off the surface of the spreader glass with gauze moistened with methanol. If spreader glass is still not clean after wiping with methanol, wipe with gauze moistened with CELLCLEAN AUTO. Insert the spreader glass with gauze moistened with water as the final step to remove the CELLCLEAN AUTO.
k. Replace the fan in its original position.
l. Close the smear unit cover.
m. Open the slide set unit cover.
n. Install the slide supply cassette.
o. Close the slide set unit cover.
p. Touch **[Cancel]** to not reset the spread glass operation count. Touch **[OK].**

4. As Needed Maintenance

Refer to the XN-3100 *Instructions for Use* for detailed and illustrated instructions for performing as needed maintenance.

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Procedural Notes and Calculations

A. If making a dilution of a patient specimen and running in XN Whole Blood mode, multiply the parameters by the dilution factor.

B. If correcting the HGB or HCT due to interfering substances, recalculate and correct the affected indices:

   1) MCHC = HGB / HCT x 100
   2) MCH = HGB / RBC x 10
   3) MCV = HCT / RBC x 10

C. Use the Help function on the SP-50 when errors and messages display. Use the error icon on the XN to display help menu.

D. While slides are being processed on the SP smear table, the START key may not be available for manual mode processing.

E. During normal processing of slides on the SP-50, Maintenance, Settings, and Shutdown functions are not available.

F. Do not place samples on a mechanical rocker. Excessive mixing may alter white cell membranes resulting in false interpretive messages.

G. For troubleshooting specifics refer to the Sysmex XN-3100 Instructions for Use.

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Limitations of Procedure

A. XN-Series Manufacturer Stated Linearity

Parameter	Range	Units
WBC	0-440.0	$x10^3/\mu L$
RBC	0-8.60	$x10^6/\mu L$
HGB	0-26.0	g/dL
HCT	0-75.0	%
PLT, PLT-F	0-5000	$x10^3/\mu L$
RET%	0-30	%
NRBC%	0-600	/100 WBC

1. Parameters that exceed these limits are flagged with "@" beside the result. The sample must be diluted, rerun and multiplied by the dilution factor.
2. Note the use of dilution for linearity on the patient report.

B. Possible Sample Interferences

1. Specimens must be free of clots and fibrin strands.
2. Marked changes in plasma constituents (e.g., low sodium, extremely elevated glucose) may cause cells to swell or shrink. The blood to anticoagulant ratio is important.
3. Red cell fragments, microcytic RBC's, or white cell cytoplasmic fragments may interfere with automated platelet counts. A fluorescent platelet may be performed to avoid this interference.
4. Cold agglutinins produce spurious macrocytosis, elevated MCH's & MCHC's, falsely decreased RBC counts and HCT's. Rare, warm agglutinins produce the same spurious results as a cold agglutinin.
5. Extremely elevated WBCs may cause turbidity and falsely increase the hemoglobin, in addition to RBC and HCT values.
6. Severely hemolyzed samples (in vitro) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
7. Severely hemolyzed samples (in vitro) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
8. Abnormal paraproteins found in Multiple Myeloma patients can falsely increase the HGB. To correct HGB perform plasma replacement. Severely icteric samples may falsely elevate the HGB value and related indices. Make a 1:5 dilution with CELLPACK.

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Limitations of Procedure, continued

9. Giant platelets and clumped platelets may falsely elevate the WBC count and falsely decrease the platelet count. Platelet clumping and/or "platelet satellitism" can occur in specimens collected in EDTA. This may falsely elevate the WBC count and falsely decrease the platelet count. There are different methods for handling samples with platelet clumping or “platelet satellitism”. These methods include vortexing of the original sample and reanalyzing or adding amikacin to the original sample and reanalyzing. Laboratories should define and validate the method(s) used by their facility.
10. Rocking specimen excessively, may affect the WBC differential.
11. Megakaryocytes may falsely increase WBC counts on automated hematology analyzers.

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